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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,469	10/31/2001	Aya Jakobovits	511582002420	3304

36327 7590 06/17/2005

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/001,469	**Applicant(s)** JAKOBOVITS ET AL.	
	Examiner MINH-TAM DAVIS	**Art Unit** 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *13 June 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *48,50 and 54-56*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 01/19/05
13. ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment of 02/22/05 is not and will not be entered, because it raises new issues. That is the addition of the language "downstream signaling effects thereof" requires new 112, second and first paragraph rejections.

The following are answers to applicant's arguments.

OBJECTION

Claims 48, 50, 54-56 remain objected to, because the amendment of claim 48 to obviated this objection is not and will not be entered.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH

Claims 48, 50, 54 remain rejected under 112, second paragraph, because the amendment of claim 48 to obviate this rejection is not and will not be entered.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

1. If claims 48, 50, 54-56 were to be entered, rejection under 35 USC 112, first paragraph of claims 48, 50, 54-56 pertaining to lack of enablement for a method for identify an agent that decrease the activity of the 101P3A11 protein of SEQ ID NO:2866, wherein said activity comprises 101P3A11-mediated cAMP accumulation or

101P3A11-mediated ERK phosphorylation remains for reasons already of record in paper of 12/16/04.

Applicant submits a Declaration by Dr Steven Kanner, arguing that antibodies that are inhibitors of the 101P3A11 inhibit the growth of prostate cancer, and thus are useful.

Applicant argues that the claims are drawn to screening assay, and thus do not require identification of substances are successful in treating cancers that express 101P3A11, but only as candidates for treatment, and only a small fraction of these candidates turn out to be viable therapeutics.

Applicant argues that Chang et al support Applicant's position. Applicant argues that the paper states that the signaling pathway which ends with ERK mediates transcription, and that the fact that the manner of mediation is not completely understood or that this particular pathway may not be the only one relevant to cancers, does not destroy the utility of the assay.

Applicant argues that the fact that a candidate compound to inhibit cAMP accumulation mediated by 101P3A11 does not have a disclosed linear pathway to inhibition of cancer growth, is irrelevant to the utility of the claimed method. Applicant argues that Applicant needs not describe the exact mechanism whereby inhibition of the activity of 101P3A11 might result in the inhibition of cancer growth.

Applicant argues that the protein is at high levels in cancers, and its activity probably contributing to growth of cancer, and therefore inhibition of this activity should inhibit cancer growth.

Applicant argues that the Office appears to require a level of certainty with respect to efficacy that is not required by the law.

The submission of the Declaration by Dr Steven Kanner is not considered and not entered, because the amendment is not entered.

Applicant's arguments set forth in paper of 02/22/05 have been considered but are not deemed to be persuasive for the following reasons:

It is noted that this is not a utility rejection.

There is no correlation between inhibition of 101P3A11-mediated cAMP accumulation or 101P3A11-mediated ERK phosphorylation and any disease, including cancer, in view that it is not clear what the result of the accumulation of cAMP by 101P3A11 is, nor what the in vivo target(s) of the ERK that is phosphorylated by 101P3A11 are. Therefore, one does not know how to use the screened agent that inhibits 101P3A11-mediated cAMP accumulation or 101P3A11-mediated ERK phosphorylation for therapeutic purposes.

Further, although SEQ ID NO:2866 is increased in concentration in prostate cancer, there is no indication that SEQ ID NO:2866, or in particular its activity such as 101P3A11-mediated cAMP accumulation or 101P3A11-mediated ERK phosphorylation is responsible for growth of prostate cancer, and thus one cannot predict that inhibition of 101P3A11 activity such as 101P3A11-mediated cAMP accumulation or 101P3A11-mediated ERK phosphorylation would result in reduction in prostate cancer growth.

For the reasons set forth above, one cannot predict whether the screened agents, based on their property of inhibition of 101P3A11-mediated cAMP

accumulation or 101P3A11-mediated ERK phosphorylation, would be useful for further testing as candidates for treatment of diseases.

Since one would not know how to use the screened agent, based on their property of decreasing 101P3 protein activity, such as inhibition of 101P3A11-mediated cAMP accumulation or 101P3A11-mediated ERK phosphorylation, one would not know how to use the claimed method.

In response to Applicant's assertion that the Office appears to require a level of certainty with respect to efficacy, it is noted that MPEP 2164.03 teaches that "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order to be enabling."

Given the unpredictability that whether there is any correlation between inhibition of 101P3 activity, such as 101P3A11-mediated cAMP accumulation or 101P3A11-mediated ERK phosphorylation and any disease, including cancer, and consequently that the agents, screened based on their inhibition of 101P3A11-mediated cAMP

accumulation or 101P3A11-mediated ERK phosphorylation, would be useful for treating any diseases, including cancer, the lack of adequate disclosure in the specification, and in view of the complex nature of the claimed invention, and little is known in the art about the claimed invention, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

2. Claims 48, 50, 54-56 remain rejected under 112, first paragraph, for lack of enablement for a method of identifying an agent that decreases 101P3A11 activity, in view that 101P3A11 encompasses "variant" of SEQ ID NO:2866, because the amendment is not and will not be entered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

June 15, 2005

Susan Ungar
Primary Patent Examiner